

P-11213.00



INVENTION DISCLOSURE FORM

WARNING: Due to the confidential nature of this document, save it as a password protected document. Do not send this document through GroupWise.

This is a WORD Template form. Press enter or tab to move to each field. Please fill out this form as completely as possible. If the allotted space is not sufficient, use a separate sheet. Have your manager sign the form and forward it to the Patent Section of the Law Department, LC340. Please attach any drawings and technical descriptions that are available and assemble copies of the background articles, books, advertisements, etc. for use by your patent attorney.

| | | | | |
|----|--|-----------------------------|----------------------|--|
| 1. | Inventor(s) Full Name(s) Daniel Sigg | Employee Number 65322 | Mail Stop B252 | Home Address (Include Zip Code) 1485 Hoyt Ave W, Saint Paul, MN 55108 |
| | _____ | _____ | _____ | _____ |
| | _____ | _____ | _____ | _____ |

2. Title of Invention: Nitric oxide releasing medical device

3. Summary of the Invention: It has been shown that nitric oxide has the ability to prevent clot formation. Nitric oxide can be released by polymers currently being used in most lead bodies and catheters (silicones, and polyurethanes), and conceivably from other polymer parts of medical devices (for example MCRD's). Certain formulations allow for chronic nitric oxide release which not only would prevent clot formation, but subsequent fibrosis. The purpose of this technology incorporated in pacing leads or other polymer parts and chronically implanted medical devices would ultimately lead to enhanced REMOVABILITY of such devices, a major largely unmet issue in particular in the management of chronic pacing leads.

4. How have others addressed this problem (List and attach any patents, books, articles, devices, Medtronic or competitor's products, or other background materials you used or which may be prior art)? See attached published references by Dr. M. Meyerhoff, University of Michigan, Ann Arbor.

5. The invention is described on pages 91 of Lab Notebook No. 10191 (Please attach copy).

6. When was a device built which included the invention? _____

Who built it? _____ Where is it? _____

Who has supporting documents? _____

Who witnessed tests? _____ When and where? _____

7. Discuss the problems which the invention is designed to solve, referring to any prior devices of a similar nature with which you may be familiar. The problem is to decrease fibrosis around the lead or catheter body, which will significantly enhance lead removability.

8. State the advantages of the invention over presently known devices, systems or processes. Major advantage, as currently there is no biologically or pharmacologically target therapy to decrease fibrosis in pacing leads.

9. List all known and other possible uses for the invention. Lead removability, use in sensors, in stents, in pacing lead MCRD's (electrodes)

10. Specifically describe the invention and its operation. You may use and attach copies of sketches, prints, photographs and illustrations which should be signed, witnessed and dated. Use numbers and descriptive names in descriptions and drawings. Either a silicone or polyurethane polymer will be manufactured which contain NO-releasing functions, such as diazenoumdiolates. These could be synthesized, and then extruded as tubing for pacing leads or other catheter materials. Other technologies to allow continuous NO (nitric oxide) release could be employed, and have been mainly described by Dr. Meyerhoff's previous research which he disclosed at a recent Forum presentation at Medtronic Cardiac Surgery. Other than the ability of releasing nitric oxide, this leads will indistinguishable from existing leads. Once implanted into the human body, pacing leads typically show signs of thrombus formation, and subsequently scar formation (fibrosis). This often leads to complicated lead removal procedures. In case of NO-releasing leads, the thrombus formation is attenuated or completely avoided, which subsequently will reduce encapsulation and fibrosis of the leads, and dramatically enhance removability.

<http://intranet4.corp.medtronic.com/legal>

12. Sale or Publication (Needed to establish the date of any printed publication, public use or sale, since no U. S. patent application may be filed after one year from such date.)

- a. If a device has been offered, or will be offered for sale, or used for profit or otherwise publicly disclosed, state when and to whom delivered and how used? _____
- b. Has a printed description of this invention been made available to persons outside the company? How and when and was use restricted (e.g. licensing agreement, non-disclosure agreement, proprietary legends, etc.)? _____

13. Inventor(s) Signature(s) (REQUIRED):

Signature

Daniel Liff

Date

12-27-02

Manager's Comments

14. How is this invention important to your products, plans or goals? _____

15. Manager's Signature (REQUIRED)

Signature

Tim Laske

Date

26 DEC 02

Manager's Printed Name Tim Laske

Business Unit CRM Therapy Delivery Advanced Concepts

Mail Stop B252

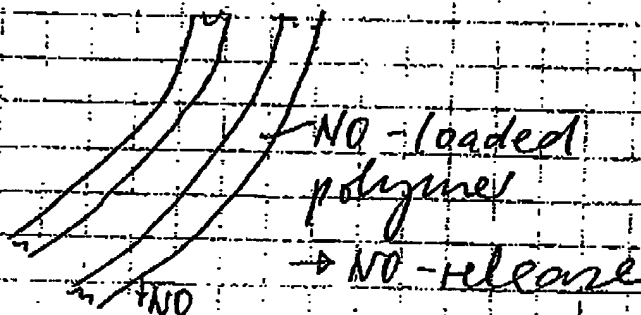
Manager: Please forward to Patent Section of Law Department, LC340, upon completion of your review.

EXTRACTION OF LEADS REMAINS A RELEVANT, AND
LARGELY UNSOLVED, CLINICAL ISSUE. THIS CONCEPT
PROVIDES A LOW COST MEANS OF MANAGING
FIBROSIS. THE CONCEPT MAY ALSO HAVE
UTILITY FOR PREVENTING FOULING OF SENSORS
AND DRUG DELIVERY CATHETERS.

NO-RELEASING LEAD OR CATHETER BODY

Nitric oxide has the ability to prevent clot formation. Technologies which are currently being used to generate NO-releasing sensors (loading of NO-precursor into polymer or generating a sustained release using endogenous precursors as described by U of Michigan) could be incorporated into either lead bodies or catheter bodies (silicone, polyurethane) or other polymeric parts, even MCD's, to prevent clotting → fibrosis and ultimately enhance REMOVABILITY.

A chronic release would be more desirable



or NO generation from body mediated products

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Invented & Understood by me,

J. M. Allen

Date

11/15/02

Invented by

Sig 65322

Recorded by

J. Sig

Date

11-13-02